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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,086	11/25/2003	Brian J. Lancaster	CRNI.111056	4915

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EXAMINER	
LUBIN, VALERIE	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,086	LANCASTER ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *EAST search history*

DETAILED ACTION

Acknowledgements

1. Claims 1-34 are pending

For reference purposes, the document paper number is 20080724

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 12-28 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. The Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); and Cochrane v. Deener, 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied. This can be done, for example, by identifying the apparatus that accomplishes the method steps, by positively reciting the subject matter that is being transformed, or by identifying the material that is being changed to a different state.

4. Applicant's method steps in claims 12 and 23 fail the first prong of the new Federal Circuit decision since they are not tied to another statutory class and can be performed without the use of a particular apparatus. Furthermore, the method steps fail to transform underlying subject matter to a different state or thing.

Claims 13-22 and 24-28, as dependents of claims 12 and 23, are rejected under the same analysis.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 23 is directed to a report, but recites a method. The claim is indefinite because it is unclear if the claim is directed to a product or a method. For examining purposes, the claim shall be interpreted as the equivalent of claim 12, a method comprising the steps of accessing clinically related data; accessing a knowledge base and selectively performing a comparative analysis of the clinically related data against the knowledge base.

Claims 24-28, as dependents of claim 23, are rejected under the same analysis.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims1-7, 9, 11-18, 20, 22-27, 29-32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenfeld et al. U.S. Patent No. 6,804,656.

10. Claim 1 is rejected, as Rosenfeld teaches a system comprising a first interface to a clinical data store (Col. 19 lines 2-44); a second interface to a knowledge base (Col. 5 lines 11-22; col. 22 lines 15-19); and an inference engine (Col 4. lines 8-13).

Claims 12, 23 and 29 are rejected under the analysis of claim 1.

11. With respect 2, Rosenfeld teaches a data warehouse (Col. 7 lines 7-10).

Claims 13, 24 and 30 are rejected under the analysis of claim 2.

12. Claim 3 is rejected as Rosenfeld teaches the data warehouse storing clinically related data from at least one clinical facility (Abstract; Fig. 8A item 9034; Fig. 8B item 9038).

Claims 4, 14 and 15 are rejected under the analysis of claim 3.

13. With respect to claim 5, Rosenfeld teaches the comparative analysis comprising an analysis of at least one key performance indicator (Col. 43 lines 11-53).

Claims 16, 25 and 31 are rejected under the analysis of claim 5.

14. Claims 6 and 7 are rejected as Rosenfeld teaches the knowledge base comprising a set of clinical guidelines with best practices (Col 3. lines 51-55; col. 5 lines 11-22; col. 26 lines 8-17).

Claims 17, 18 and 26 are rejected under the analysis of claims 6 and 7.

15. Claim 9 is rejected as Rosenfeld recites outcome information based on clinically related data and the knowledge base (Col. 5 lines 11-22; col. 43 lines 11-21).

Claims 20, 27 and 32 are rejected under the analysis of claim 9.

16. Claim 11 is rejected as Rosenfeld teaches storing the comparative analysis (col. 20 lines 1-5).

Claims 22 and 34 are rejected under the analysis of claim 11.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 8, 10, 19, 21, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld et al. U.S. Patent No. 6,804,656.

19. For claim 8, Rosenfeld recites best practices data comprising pharmaceutical and medical procedure information (Col. 7 lines 24-67); and he discloses historical files (Col. 20 lines 42-46). A predictable result of Rosenfeld would therefore be to include historical outcomes information in best practices for reuse when appropriate (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 19 is rejected under the analysis of claim 8.

20. With respect to claim 10, Rosenfeld discloses maintaining a performance mortality measure (Col. 16 lines 4-6); and outcome algorithms for antibiotic cost information (Col. 7 line 31). A predictable result of Rosenfeld would be to include whatever information necessary (e.g. patient mortality and morbidity information, clinical cost information etc.) to better treat a patient. (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claims 21, 28 and 33 are rejected under the analysis of claim 10.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a) Thangaraj et al. U.S. Pre-Grant Pub No. 2003/0208378 discloses many of Applicant's limitations such as clinical data repository, and analysis engine and key performance indicators.

b) Bond et al. U.S Patent No. 6,177,940 discloses recites a system for data input and storage for correlation against group data.

c) Papageorge U.S. Patent No. 6,584,445 recites output information including cost information depending on mortality and morbidity rates.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626